

### Remarks

#### I. Introduction

It is respectfully requested that this Amendment After Final Rejection be entered and made of record. It is believed that the following amendments and remarks place the application in a form for allowance. The following amendments and remarks at least place the claims in a better form for appeal. No new matter is presented, as such the amendment is proper under 37 C.F.R. § 1.116.

Claims 7-12, 35, and 36 are presented for examination. Claims 13-34 have been withdrawn as being directed to a non-elected invention. Claims 7-12 and 35 have been amended to specify that Applicants' compositions are "biodegradable". Claim 36 has further been amended to correct a typographical error in the formula II. Line 24 of p. 7 in the specification has been amended to be consistent with the formula of claim 36. No new matter has been added.

#### II. Election/Restrictions

Group II, claims 13-34 have been withdrawn without prejudice as being drawn to a non-elected invention in accordance with the Examiner's restriction requirement.

#### III. Claim Rejections - 35 U.S.C. § 112, Second Paragraph

Claim 36 has been rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In this regard, the Examiner notes that claim 36 sets forth that R is  $(CH_2)_nCOOH$  in formula II. However, formula II does not set forth an R symbol. Claim 36 has now been amended to delete reference to "R" to make it consistent with formula II. Since this amendment merely constitutes correction of an obvious typographical error, the claim has not been narrowed, and no new matter has been added. The specification has also been amended accordingly.

Applicants therefore respectfully request that the rejection under Section 112, second paragraph be withdrawn.

#### IV. Claim Rejections - 35 U.S.C. § 102

##### A. Bogan et al.

Claims 7-12, 36 and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by Bogan et al. (U.S. Pat. No. 4,590,265). Applicants respectfully traverse this rejection.

As indicated by the title and throughout the specification, the present invention is drawn to biodegradable, oxidized cellulose esters. Claim 36 from which claims 7-12 depend has now been amended to explicitly state the biodegradable nature of Applicants' compositions.

As a preliminary matter, the Examiner states that Applicants' claimed compositions are anticipated by the cellulose acetate butyrate structure set forth at the bottom of column 6 in the Bogan et al. patent when X represents H; when w is less than 1.0; when R' and/or R'' represents  $(CH_2)_nCH_3$ , n is 0 and 2; and when x and y are 0.1-1.9. (Office Action p. 4). It is believed the Examiner intended to reference the structure at the bottom of column 16 rather than column 6. This structure does not anticipate the claimed invention because it only represents a segment of the Bogan et al. carboxylated product (Col. 16, line 49). In any event, a chain cleavage reaction soon follows leading to the formation of a lactone as shown in column 17. Such structures do not anticipate the claimed invention.

The present invention describes for the first time the synthesis of biodegradable cellulosic polymers. (See attached Supplemental Declaration of Dr. Vijay Kumar, paragraph 2). In comparison to previously made oxidized cellulose esters, the products of this invention offer a new class of biodegradable polymers that undergo hydrolysis by enzymatic and/or chemical means *in vivo* and *in vitro*. (Spec. 4, lines 6-10; Supp. Decl. V. Kumar, para. 3). They may therefore be used as biomaterials and as drug carriers in medicine, pharmaceuticals, agriculture, and veterinary fields. (Spec. bottom of p. 5 to top of p. 6; Supp. Decl. V. Kumar, para. 3). In addition, these oxidized cellulose esters are less expensive to produce than some of the most commonly and widely used biodegradable polymers, such as poly(lactide-co-glycolide) copolymer. (Spec. p. 6, lines 1-3; Supp. Decl. V. Kumar, para. 4).

While others in the art have successfully synthesized carboxylated cellulose esters, such compounds are not biodegradable. (Supp. Decl. V. Kumar, para. 5). Studies show that the carboxyl content and degree of polymerization (DP) of oxidized cellulose play important roles in the degradation of oxidized cellulose *in vitro* and *in vivo*. (Spec. p. 2, lines 22-24; Supp. Decl. V. Kumar, para. 6). In general, the higher the carboxyl content, or the lower the DP, the faster the rate of degradation of oxidized cellulose. (Spec. p. 2, lines 24-25; Suppl. Decl. V. Kumar, para. 6). Compared to other biodegradable polymers, oxidized cellulose has received little consideration as a potential biomaterial or drug carrier. (Spec. p. 3, lines 14-17; Supp. Decl. V.

Kumar, para. 7). This is because it is practically insoluble in organic solvents and water, and hence, poses little or no formulation flexibility. (Spec. p. 3, lines 17-18; Supp. Decl. V. Kumar, para. 7).

Recently, U.S. Patent No. 5,973,139 (Lee et al.) disclosed a process for producing carboxylated cellulose esters using oxidized cellulose materials containing about 0.14-0.3% w/w of carboxylic content. (Spec. p. 3, lines 19-22; Supp. Decl. V. Kumar, para. 8). In this process, the starting cellulose source is first esterified and then hydrolyzed to give the product. (Spec. p. 3, lines 22-23; Supp. Decl. V. Kumar, para. 8). The carboxylated cellulose esters prepared by this method are useful in the development of coating formulations that can be applied to paper, plastic, metal, wood, gypsum board, concrete brick, masonry or galvanized sheets. (Spec. p. 3, lines 24-27; Supp. Decl. V. Kumar, para. 8).

Another previous method in the art for preparing carboxylated cellulose esters uses cellulose acetate butyrate as a starting material. (Spec. p. 3, lines 28-29; Supp. Decl. V. Kumar, para. 9). The carboxylic groups are then introduced by treating the polymer with ozone. (Spec. p. 3, lines 29-30; Supp. Decl. V. Kumar, para. 9). The disadvantage to the carboxylated cellulose esters prepared according to this method, however, is that they are not biodegradable. (Spec. p. 3 line 31 to p. 4 lines 1-2; Supp. Decl. V. Kumar, para. 9). This is exactly the method by which the carboxylated cellulose esters of Bogan et al. are prepared, i.e. cellulose acetate butyrate is reacted with ozone. (Bogan Col. 12, lines 66-68 and Col. 13, lines 66-67; Supp. Decl. V. Kumar, para. 10). Thus, the non-biodegradable cellulosic polymers of Bogan et al. are inherently different from that of the claimed invention. (Supp. Decl. V. Kumar, para. 10).

The non-biodegradability of the polymers of Bogan et al. is also illustrated by the intended uses of their compositions. (Supp. Decl. V. Kumar, para. 11). Specifically, the Bogan polymers are intended for use as pigment dispersions (Col. 17, line 44), metal coatings (Col. 18, line 34), ink compositions (Col. 20, line 51), and wood coatings (Col. 22, line 9). (Supp. Decl. V. Kumar, para. 11). One skilled in the art would realize that such products should not be biodegradable since they must remain intact in order to exhibit permanent sealing/protective qualities. (Supp. Decl. V. Kumar, para. 11).

Applicants' oxidized cellulose esters are further distinguished from those of Bogan et al. since they do not include lactone functional groups. (Supp. Decl. V. Kumar, para. 12). Bogan et

al. note that their carboxylated cellulose esters including the acetates, butyrates and propionates (termed "XAE") contain a lactone level of from about  $4.52 \times 10^{-5}$  to about  $6.13 \times 10^{-4}$  moles of lactone moiety per gram of XAE. (Col. 1 lines 66-68 and Col. 2 lines 12-14; Supp. Decl. V. Kumar, para. 12). In contrast, Applicants' oxidized cellulose esters do not include lactone moieties, as evidenced by the claimed structures. (Supp. Decl. V. Kumar, para. 12).

Claims 7-12 and 36 are also not rendered obvious by Bogan et al. There is no teaching or suggestion in Bogan et al. to synthesize Applicants' claimed biodegradable oxidized cellulose esters since the Bogan et al. compounds cannot be biodegradable if they are to be used for their intended purposes. (Supp. Decl. V. Kumar, para. 13).

**B. Lee et al.**

Claims 35 and 36 were rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (U.S. Pat. No. 5,973,139). As already noted above, the compositions of Lee et al. also do not read on Applicants' claimed compounds since the Lee compounds are not biodegradable. (Spec. p. 3, lines 19-27; Supp. Decl. V. Kumar, para. 14). The non-biodegradability of the Lee et al. compounds is evidenced by the low carboxylic content of its compounds (0.14-0.3% w/w) as well as the intended uses of the compounds. (Spec. p. 3, lines 21-27; Supp. Decl. V. Kumar, para. 15). More specifically, the intended uses of the Lee compounds, similar to those of Bogan et al., include coating formulations for paper, plastic, metal, wood, gypsum board, concrete brick, masonry or galvanized sheets. (Col. 6-Col. 8; Supp. Decl. V. Kumar, para. 15).

For these reasons, claims 35 and 36 are not rendered anticipated by Lee et al. Applicants therefore respectfully request that this ground of rejection be withdrawn.

Claims 35-36 are also not rendered obvious by Lee et al. There is no teaching or suggestion in Lee et al. to synthesize Applicants' claimed biodegradable oxidized cellulose esters since the Lee et al. compounds cannot be biodegradable if they are to be used for their intended purposes. (Supp. Decl. V. Kumar, para. 16 ).

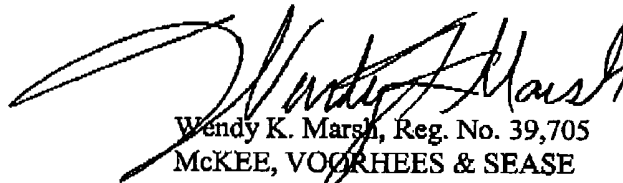
**V. Conclusion**

It is believed the application is in a prima facie condition for allowance. Allowance is therefore respectfully requested.

It is believed that a two month extension of time is due in connection with this Amendment (June 9, 2004 to August 9, 2004). Accordingly, please charge Deposit Account 26-

0084 in the amount of \$210.00 for the two-month extension fees. No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,



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